May 24, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: [Docket No. 01D-0044]
Medical Devices Draft Guidance for CLIA Criteria for Waiver; Availability

To Whom It May Concern:

I have been a Medical Technologist for 29 years. I have been a State Agency and HCFA surveyor for 19 years. I am alarmed at FDA's stance on weakening the CLIA regulations for waiver. The intent of the regulations was to ensure safe and accurate/reliable laboratory testing. With the increased number of waived tests being allowed, this assurance is not there. The following are my comments to the Draft Guidance Package:

1) Laboratory tests are simple and accurate as long as testing personnel use the methodologies correctly and employ quality control methods. However, based on CLIA survey data, this has not been the case in non-regulated laboratories (for example, physician office laboratories {POL}).
   a) Staff do not read manufacturer's instructions;
   b) Staff are not trained using manufacturer's instructions, its "teach one-do one";
   c) Manufacturer's instructions are thrown away, or they are outdated; or they don't match the test kit currently in use;
   d) Staff cut urine dip sticks in half and perform tests; strep tests – reagents are added in reverse order; manufacturer's package reagents with minimal labeling thus setting-up the opportunity for staff to mix reagents from different test methods (urine pregnancy test kit and strep test kit);
   e) Staff store urine dip sticks incorrectly (open bottles);
   f) Staff don't know how to read the urine dip sticks;
   g) Staff uses expired reagents and/or mix reagents from different lot numbers for the same test method.
   h) Nothing is "fool proof", there will always be someone to find away to subvert the test method. Any of the waived tests (urine dipstick, glucometers, strep, etc) can cause harm when done incorrectly.
2) The FDAMA should not supercede CLIA regulations. The CLIA regulations are specific and FDA should adhere to those regulations and not change them. If changes are needed, then it should be HCFA's decision in concert with CDC, FDA, CLIAC, etc. It is not the responsibility of to interpret CLIA regulations.
3) One clarification should be made in the CLIA regulation: home use and prescription home use. They should be defined as "used in a patient's home by the patient". It should not infer that home use waiver can be used in a medical facility (clinic, POL, hospital, etc). If test kits are to be used in a medial setting, they must be subject to CLIA inspections and not waived.
4) The review process should not be limited to only the data submitted by the manufacturer. The review process should include actual "user data" that is currently available: actual proficiency testing data, HCFA studies (Waived/PPMP Project); California study on laboratory personnel; CLIA survey data.
5) The HCFA Waived/PPMP Project identified some serious problems: no instructions, untrained personnel; no training, etc. This data should be used to make decisions on how well laboratories and facilities use waived tests and follow instructions. This data demonstrates the "real world" usage of waived and PPMP tests.

6) The waived process should not be automatic at the time of the PMA or 510K approval. If a manufacturer wants to waive a test method, they should initially be categorized as moderate or high. Then after some time (maybe 2years), submit their test kit, method, instrument for waived review and base the review on actual "user data" for the time period. Currently some of the waived strep test kits and potential waived methods do not do well on proficiency testing or quality control use.
7) Have a post-approval surveillance requirement. Actual "user data" or studies should be included in the review process to determine continued waive status. If data shows problems, then "un-waive" the test method.
8) In all waived tests, the use of quality control should be required. Use "must", not shall or is recommended.
9) Because of the personnel performing waived tests, there must be a requirement for documentation of the training of personnel on the use of the method.
10) Because the waived tests are exempt from CLIA standards and oversight, ensure the quality of the test method. The quality of the waived methods must be at a higher level to offset the inexperience of testing personnel.
11) FDA should be cautious in increasing the numbers of waived tests. Please do not increase the risk to patients due to failure of personnel to follow test instructions. Personnel are self-taught with very little or no direct supervision. There is a great deal of turnover. They have very little understanding of laboratory theory. Therefore, education of staff, orientation, training and supervision is the key.
12) There needs to be more research/studies on the impact of erroneous test results due to waived tests or laboratory tests in general before it should be used as criteria for waiver.
13) Waiver routes should all be equivalent. Home use waiver is not equivalent to other waiver approval criteria. This is a double standard and a back-door for the waiver approval.
14) Waiver data from the manufacturer should be based on scientific studies. Use reference methods, clinical evidence or correlation, specificity, sensitivity, etc.
15) FDA should consider the use of the test method; screening, monitoring, diagnostic. Diagnostic methods should not be waived.

I appreciate the opportunity to comment.

Sincerely,

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